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DEPARTMENT OF THE NAVY
Bureau of Medicine and Surgery
Washington, D.C. 20372

BUMEDINST 3900.6A
MEDCOM- ~~BUMED-00C8~~ 020
4 February 1982

√Research

BUMED INSTRUCTION 3900.6A

From: Chief, Bureau of Medicine and Surgery
To: All Ships and Stations

R) Subj: Protection of human subjects

Ref: (a) SECNAVINST 3900.39A B
~~(b) BUMEDINST 3900.3B~~
(c) NAVMATINST 3910.15A
(d) ~~BUMEDINST 6710.49D~~ NMCI 6710.9
(e) ~~BUMEDINST 6000.4C~~ ~~NMCINST 6000.4~~
(f) MANMED article 20-7
(g) SECNAVINST 5212.5B
(h) SECNAVINST 5211.5C

Encl: (1) Suggested Format for Recommendation of
R) Committee for the Protection of Human Subjects
R) (2) Suggested Format for Application to Committee for the Protection of Human Subjects
(3) Suggested Format for Privacy Act and Con-
A) sent Statements

1. Purpose and Scope. To provide guidance and establish
R) procedures for the protection of human subjects in (a) all studies conducted at Navy activities regardless of funding sources, (b) Navy-supported studies conducted in non-Navy Federal activities, and (c) studies conducted by contractors using Navy or Marine Corps personnel or Navy Department employees. It supplements references (a) through (f).

2. Cancellation. BUMEDINST 3900.6.

3. Responsibilities. Reference (a) assigns to the Chief,
R) Bureau of Medicine and Surgery approval authority for all proposed Navy in-house studies involving the use of human subjects and all proposed contract studies using as subjects Navy or Marine Corps personnel or Navy Department employees which do not require approval of the Assistant Secretary of the Navy (Research, Engineering, and Systems) (ASN (RE&S)). Prior to granting approval, the Chief, Bureau of Medicine and Surgery shall ascertain that the provisions of reference (a) relative to consent standards, studies, and safeguards have been met. The BUMED Medical Department Education and Training Division (MED-28) is authorized to approve by direction studies utilizing human subjects which are to be supported by the Navy's Clinical Investigation Program. The Special Assistant for Medical Research and Development (MED-00C8) is authorized to approve by direction all studies using human subjects which are within the scope of this instruction and which are not intended to be part of the Clinical Investigation Program.

4. Procedures (R

a. All proposed studies involving the use of human subjects shall be reviewed by the performing activity's Committee for the Protection of Human Subjects (CPHS) as described in reference (a). The CPHS must include at least one Navy enlisted member if any of the subjects utilized in a given study are from the enlisted community.

b. Ongoing studies involving the use of human subjects (R
which have been previously reviewed in accordance with the provisions of reference (a) shall be reviewed by the activity's CPHS and submitted for approval within 90 days following promulgation of this instruction. Those proposals which are approved by the CPHS and do not require approval of ASN (RE&S) are to be forwarded via the chain of command to the Chief, Bureau of Medicine and Surgery (ATTN: MED-28 or MED-00C8) together with completed copies of enclosures (1) and (2). Proposals which require ASN (RE&S) approval shall be submitted via the Chief, Bureau of Medicine and Surgery (ATTN: MED-28 or 00C8), the Deputy Chief of Naval Operations (MPT) (ATTN: Op-01B4) or Commandant of the Marine Corps (ATTN: Chief of Staff for Manpower), and the Chief of Naval Operations (Director, RDT&E).

c. Following review, the Medical Department Education and Training Division (MED-28) or the Special Assistant for Medical Research and Development (MED-00C8) shall: forward information copies of approved proposals not requiring ASN (RE&S) clearance to offices specified in paragraph 12 of reference (a); forward proposals requiring ASN (RE&S) clearance with appropriate endorsement; and notify the performing activity of approval/ disapproval recommendations. (R

5. Maintenance of Records. All records associated with a (R
study involving the use of human subjects shall be retained permanently at the performing activity in accordance with references (a) and (g). Records shall include the names and Social Security numbers of volunteers and shall be maintained in accordance with the provisions of reference (h). In addition a copy of the signed consent statement and privacy act statement (enclosure (3)), shall be filed in the subject's health record, together with sufficient documentation to clearly identify by name or

code any drugs administered, whether investigational or not, investigational procedures performed, and significant observations, including any adverse effects. The maintenance of such records shall be a matter of primary concern during laboratory and program review or inspection.

R) **6. Reporting of Complications.** Activities shall notify BUMED (MED-28 or MED-00C8) by message or speedletter within 24 hours of any accident, untoward drug reaction, appearance of disease or injury which may occur as a result of using human subjects in an experimental study, and the medical or dental treatment, including hospitalization, provided.

7. Action Activities shall take such action as required to implement procedures prescribed by this instruction. (D

8. Report. Report control symbol MED 3900-3 has been assigned to the Complication in Study Using Human Subjects report required by paragraph 6 of this instruction. This report has been approved by the Chief of Naval Operations for a period of 2 years from the date of this instruction. (A

J. WILLIAM COX

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SUGGESTED FORMAT FOR RECOMMENDATION OF COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

Title of Study:

Principal Investigator:

Approximate Dates of Study: From: _____ To: _____

Recommendation: Approve _____ Disapprove _____

In our opinion the protocol and safeguards described on the attached application meet the standards of the Department of the Navy as set forth in SECNAVINST 3900.39A - namely, that the use of humans as experimental subjects be limited to those situations in which voluntary, informed consent is obtained; and that such use be confined to research projects and clinical investigations which are necessary, scientifically sound, reasonably safe, and in which the benefit to be derived clearly justifies the risk incurred by the subject.

COMMITTEE MEMBERS

			Approve	Disapprove
(Typed name)	(Signature)	(Date)	(Initial)	(Initial)

Note: When the recommendation of the committee is not unanimous, dissenting members must append a statement of the reason(s) for their nonconcurrence hereto.

SUGGESTED FORMAT FOR
APPLICATION TO COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

1. Title of Study.

2. Principal Investigator.

   Associate Investigator.

3. Location(s) where study will be performed.

4. Approximate dates of study: From: _____ To: _____

5. A. Has this protocol been submitted for approval to committee(s) for the protection of human subjects at other institutions concerned?

   B. Disposition by other committee(s):

6. Description of study

(a) Describe briefly the procedures to be employed in the proposed study. Specify the clinical conditions, sex, age, and other relevant characteristics of individual subjects or population to be observed. Indicate the number of subjects to be involved and the number of times observations will be made. If medication is to be used, cite its proprietary and/or generic name, dose, route of administration, and name of person responsible for its administration. Describe in detail any discomfort, stresses, or aggravations of a chemical, physical, biological, psychological, or other nature which will be imposed. Cite your own or your associate investigator's experience with research of this kind.

(b) Outline the possible benefit or advantage of the proposed study to the individual subject, group of subjects, and society.

(c) Outline possible risks to subjects. An individual is considered to be "at risk" if exposed to the possibility of harm, physical, psychological, sociological, or other, as a consequence of any act or omission which goes beyond the application of established and accepted methods or procedures which are in an individual's best interests, or which increases the probability of harm inherent in daily life or in occupation or field of service. Document with appropriate references. Indicate procedures and safety measures which will be used to assess and reduce risks. Specify names of physician(s) responsible for medical supervision.

(d) Explain the manner in which you will obtain informed consent and the measures to be taken to protect the rights of privacy of the subjects. Attach copies of the consent and Privacy Act statements you intend to use.

(e) What measures will be taken to enable the subject to omit specific procedures or to leave the study?

(f) Indicate what changes you are likely to introduce during the course of the study; e.g., choice of subjects, obtaining of informed consent, procedures to be employed, drugs, or experimental design.

(g) If this is a continuation of a project previously reviewed by the committee, indicate any changes in experimental design which may affect the risks or benefits to subjects. Summarize any untoward effects during the period since your application was last reviewed by the Committee.

(h) Describe rationale for conducting study on human subjects or populations and give reasons why work could not be done in animal models. Summarize the nature and results of studies done previously in animals.

(i) Describe the intent (or lack of intent) to share the results of the study with the volunteer subject(s).

(j) If applicable, describe the criteria for breaking double blind codes to ascertain possible excessive risk to experimental subjects.

SUGGESTED FORMAT FOR
CONSENT STATEMENTS

From: (Name of volunteer)

To: (Name of activity)

Subj: Consent to participate voluntarily in an experiment

Encl: (1) Details of experiment*
(2) Subject's inquiries (if any) and responses

1. I hereby volunteer to participate as a subject in an experiment entitled "_____." I understand that the adequacy of safety measures has been certified by the Committee for the Protection of Human Subjects and that authority to use human volunteers has been granted by the Chief, Bureau of Medicine and Surgery.

2. Details of the experiment, which are described in enclosure (1), have been explained to me. The explanation has included:

a. A description of the procedures to be followed and their purposes, including identification of any procedures which are experimental.

b. A description of any attendant risks and discomfort.

c. A description of expected benefits.

d. A disclosure of any alternative procedures that might be advantageous to me.

3. My consent is given as an exercise of free will, without force or duress of any kind. Any inquiries I have concerning the experiment and the answers provided are recorded in enclosure (2). I understand that my consent to participate does not release the United States from any possible future liability attributable to the experiments. I understand that I will be free to withdraw my consent and to discontinue my participation in the experiment, or any part thereof, at any time without prejudice to myself or to my military or civilian career. In making my decision to volunteer, I am not relying upon any information or representation not set forth in this statement or in the enclosure thereto.

* Appropriate sections of the application to the CPHS.

SUGGESTED FORMAT FOR
PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or performance impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the experiment described herein will be retained permanently at (name of performing activity) and salient portions thereof will be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph and I have been informed that failure to agree to such disclosure may negate the purposes for which the experiment was conducted.

_____ _____
(Signature) (Signature of Witness)

_____
(Type name, grade or rate)

_____
(Date of birth)